which comprises between about 5 mg and 100 mg per day of an active composition comprising the dextro optically active isomer of 1-(meta-trifluoromethylphenyl)-2-ethylaminopropane or a physiologically acceptable salt thereof in admixture with an inert non-toxic carrier.

~~3~~. (Amended) A method of claim ~~2~~ 1 wherein the dosage of the active isomer [composition in the composition of claim 1] ranges from [5 to 100 mg] 10 to 60 mg per day.

REMARKS

The specification has been amended to correct the chemical identity of fenfluramine. The specification claims have also been amended to eliminate the confusion regarding the optical isomers of fenfluramine. Accordingly, the rejection under 35 USC 112, first paragraph, regarding these matters should be withdrawn.

The claims have been rejected under 35 USC 112, first paragraph, for use of the term "salt". The Examiner's attention is called to page 3, lines 25 through 29, wherein representative suitable salts are set forth. It is submitted that the person skilled in the art would have no difficulty in determining the meaning of the claim language, particularly in view of the specification. Accordingly, this ground of rejection should be withdrawn. Claims 5 and 6 also have been rejected under 35 USC 112, first paragraph, for failure to recite a specific therapeutic condition as well as requisite method parameters, e.g. route and timing of administration, dosage

and frequency. It is submitted that this ground of rejection should be withdrawn since the claims specifically recite the rate of dosage administration, thereby providing specific definition to the timing of administration, dosage and frequency. The route of administration is not essential to the process of this invention and representative suitable routes of administration are set forth at page 4, lines 1 through 16. In addition, claims 5 and 6 specifically define the nature of the affliction of the human patients being treated in accordance with this invention. The nature of this affliction is specifically set forth at page 4, line 24 through page 5, line 13. Accordingly, the rejection based upon 35 USC 112 should be withdrawn.

Claims 5 and 6 have been rejected under 35 USC 102 or 35 USC 103 over Beregi et al. It is the Examiner's position that Beregi et al inherently obtained the same effect now claimed by applicants. In addition, it is the Examiner's position that the data provided in the specification shows no unexpected effect in humans. The Examiner's attention is called to in re Shetty, 195 USPQ 753. In that case, the claims on appeal related to certain adamantane compounds and the use of the compounds for curbing appetite. The rejection of the composition claims is based upon the fact that the claimed compounds were structurally similar to prior art compositions in an obvious manner. The basis for rejecting the process claims is that the structurally similar adamantane compounds of the prior art have been used as an antiviral agent, as a hypoglycemic agent or as a central nervous depressant. The Board of

Appeals took the position that the prior art disclosures of dosage of the adamantane compounds corresponding to applicants' disclosed appetite-curbing dosage. (Therefore, inherently appetite-curbing). The Court of Customs and Patent Appeals reversed the Board of Appeals as to the process claims since inherency was quite immaterial as the prior art cited in the rejection failed to show a reasonable expectation or some predictibility that the adamantane compounds were effective as an appetite suppressant. The Court further stated that mere hindsight asserting that corresponding dosages render applicants' method obvious is untenable. There was no prior art which suggested a use of the adamantane compounds much less a dosage for curbing appetite. The prior art cited against this application contains no suggestion of the utility of fenfluramine compounds in treating animals to selectively reduce their craving for carbohydrates while rendering protein intake unchanged. Furthermore, there is no suggestion in the prior art that utilizing the dextro isomer of fenfluramine is superior to the levo isomer for this prupose. In addition, it is submitted that the specification provides sufficient data for the person skilled in the art to conclude that d-fenfluramine has the effect of selectively reducing craving for carbohydrates while rendering protein uptake unchanged. It is well known in the art that experiments with animals such as rats have a correlated effect as applied to humans. Accordingly, this ground of rejection should be withdrawn.

The claims in the application have been rejected under 35 USC 102 or 35 USC 103 over the three Wurtman et al

articles alone or in combination with Beregi et al. All of the Wurtman articles relate to the effect of racemic mixture of fenfluramine on food consumption both as regards quantity and as regards type. As shown by reference T and S, the racemic mixture of fenfluramine has the effect of lowering carbohydrate consumption while sparing protein consumption. There is no suggestion in any of the Wurtman et al articles that either the d form or the l form of fenfluramine is any better than the racemic mixture or is any better than the other racemic form. Applicants, for the first time in the art, show in this application that the d form is, in fact, the active isomer for reducing carbohydrate consumption while sparing protein consumption. Furthermore, applicants have shown that the dosage of the d form of fenfluramine is critical in that carbohydrate consumption is not reduced significantly when utilizing dosages either above or below the claimed range. Beregi et al does not supply the deficiencies of the Wurtman et al references since there is no disclosure nor suggestion that fenfluramine has an effect of reducing carbohydrate consumption while sparing protein consumption and furthermore contains no suggestion that the d form of the compound is the most active form for this particular purpose. Accordingly, it is submitted that applicants' claims define patentable subject matter and an early notice of allowance to that effect is respectfully requested.

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Respectfully submitted,

By _____

Paul J. Cook
Registration No. 20, 820
54 Pine Street
Manchester, MA 01944
Tel. (617) 526-7149
Attorney for Applicants

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